Directed Medication Syst m and M thod

This application is a continuation-in-part of Application No. 10/411,459, filed April 10, 2003.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates generally to medical diagnostic test kits. Particularly, the present invention relates to a system to minimize adverse drug events and to maximize drug effectiveness.

2. Description of the Prior Art

[0002] Numerous medical tests are commercially available for use in the home. Two illustrative examples include medical test kits that are used to discover an individual's blood sugar, i.e. glucose, level at a particular time, or an individual's hormone level at a particular time for pregnancy testing.

[0003] The glucose test kit allows a diabetic to test his/her blood sugar and adjust his/her daily insulin dosages accordingly without consulting a doctor or other medical personnel. To initially learn to take blood and use a personal glucose test kit, a diabetic may get trained by a nurse or other medical personnel. Not all personal test kits require the taking of blood or other internal body fluid. For example, personal pregnancy test kits are commercially available that allows a woman, in the privacy of her own home, to test her urine for the presence of a pregnancy hormone, human chorionic gonadotropin.

[0004] DNA test kits that are used to determine familial relationships are also commercially available. DNA test kits use DNA sequencing technology to determine the familial relationship of an individual. DNA sequencing is the determination of the order of nucleotides (the base sequence) that exists in a DNA molecule of an individual.

[0005] As one example of DNA lineage testing, GeneTree™ offers DNA Personal Paternity Tests. DNA Personal Paternity Tests can be used in the home to statistically determine the likelihood of a particular man being a child's father. The GeneTree™ DNA Personal Paternity Tests utilize cheek cells collected with colored swabs where one color indicates an alleged father and a second color indicates the subject child. The colored swabs are placed in coordinating colored envelopes that match the color of the user's swab. The envelopes are then sent to a laboratory where genetic testing is performed according to standard procedures.

[0006] Unfortunately, most medical test kits on the market today are used for determining events that have already occurred. These test kits determine the existence of a condition such as low blood sugar, pregnancy, etc., or to determine the statistical probability of a genetic link between two or more individuals.

[0007] There exists today a problem with the system used for the development of new drugs and drug treatments. Currently, pharmaceutical companies are limited to developing drugs using a one-size-fits-all system. This system allows for the development of drugs to which the average patient will respond. Unfortunately, some patients have a severe negative reaction to a prescribed drug while some

patients may have no response to the medication at all. In the industry, this is called an adverse drug reaction.

[0008] A 1998 study of hospitalized patients published in the Journal of the American Medical Association reported that in 1994, adverse drug reactions accounted for more than 2.2 million serious cases and over 100,000 deaths. An adverse drug reaction is one of the leading causes of hospitalization and death in the United States. Currently, there is no simple way to determine if people will respond well, badly or not at all to a medication.

[0009] With the advent of the Internet and the proliferation of medical-related information, patients are becoming more aware of the seriousness of adverse drug reactions. They may even know someone who has suffered such an event. Harvard Business School Professor Regina Herzlinger, writing in the July 2002 issue of the Harvard Business Review, reports that patients are demanding better, more tailored treatments. The article further notes that a report in the Journal of the American Medical Association showed that screening drugs against a person's genetic makeup could reduce many dangerous reactions. The AMA report revealed that more than half of the 27 drugs frequently cited for causing adverse reactions were linked to genetic variations in a patient's ability to metabolize the drugs.

[0010] Drug metabolism in the body makes drugs more readily excreted in the urine or bile. Many drugs are metabolized in the liver or kidney and the function of these organs along with certain enzymes can affect drug metabolism. One common way of metabolizing drugs involves the cytochrome P450 enzymes. Many drug

interactions are a result of inhibition or induction of cytochrome P450 enzymes that increase or decrease the retention of drugs in the body. A physician can better anticipate and manage adverse drug reactions in a patient by knowing an individuals genetic variation regarding the cytochrome P450 enzymes.

[0011] Therefore what is needed is a directed medication system and method that is minimally invasive. What is also needed is a directed medication system and method that is used to predict a patient's potential of an adverse medical reaction to a particular drug treatment/medical therapy. What is even further needed is a directed medication system and method that is used to predict the efficacy of a particular medication/medical therapy within the user's body. What is still further needed is a directed medication system and method that minimizes the potential for an adverse drug event.

SUMMARY OF THE INVENTION

[0001] It is an object of the present invention to provide a directed medication system and method. It is also an object of the present invention to provide a directed medication system and method that can be utilized by any individual. It is a further object of the present invention to provide a directed medication system and method that is minimally invasive. It is still a further object of the present invention to provide a directed medication system and method that will predict the likelihood of a patient's adverse medical reaction to a particular drug treatment/medical therapy. It is another object of the present invention to provide a directed medication system and method

that will predict the efficacy of medications within the user's body. It is yet another object of the present invention to provide a directed medication system and method for determining the likelihood of potential liver dysfunction in individuals as well as cardiac toxicity, pulmonary toxicity and other organ toxicity.

[0012] The present invention achieves these and other objectives by providing a directed medication system and method that includes a drug metabolism test component and a prescription instruction component. The drug metabolism test component includes a medical test kit for determining the function of internal organs, or the presence of particular enzymes or blood and urine chemistry markers associated with drug metabolism.

[0013] The preferred drug metabolism test component includes a sample container comprising a hinged folder having a first and a second sample holding pads, a first and a second sample collection devices corresponding to the first and second sample holding pads, and an instruction sheet. The test component may also include a desiccant pillow and an outer pouch sized to contain both the utilized sample container and desiccant pillow.

[0014] The hinged folder of the sample container has a first surface with locations for the first and second sample holding pads, and a second surface that overlays the first surface. The sample holding pads of the sample container first surface are protected by the second surface. The sample container first surface has indicia markings below the first and second sample holding pads. The indicia markings indicate the proper location for placing a first and a second cell sample upon the

appropriate sample holding pad. The first and second surfaces of the sample container are approximately of equal size.

[0015] The second surface may have an extended portion, i.e. a securing tab, for securing the second surface to the first surface. The securing tab may either fold over a lower portion end of the first surface or may be inserted into a slit of the first surface below the first and second sample holding pads. The securing tab may also have a pressure-sensitive adhesive to secure the tab against the back side of the first surface of the sample container near the lower portion end of the first sample container surface below the first and second sample holding pads. Alternatively, the second surface may have a coating of a pressure-sensitive adhesive along a portion adjacent an edge of the second surface for adhering to the first surface.

[0016] The sample holding pads on the first surface of the sample container are sized and shaped to receive enough quantity of biological sample to achieve accurate results for the desired test. In the preferred embodiment, the biological sample is a buccal cell sample. In this instance, it is to determine the presence of risk markers in a person's DNA that predicts a high probability of possible liver dysfunction or other organ dysfunction leading to an adverse drug reaction. First and second sample holding pads may be any shape and may each be a different shape. The sample holding pads are absorbent and impregnated with chemicals to lyse cell membranes on contact, to immobilize and stabilize nucleic acids (DNA and RNA), and to inactivate bacteria and viruses. The sample holding pads allow biological cell samples to be collected, transported and stored at room temperature.

[0017] The first and second sample collection devices are cell collection devices and specifically correspond to the first and second sample holding pads. The first and second cell collection devices are generally flat, elongated rectangular swabs composed of an inert, i.e. non-reactive, material that will not introduce contaminants onto the sample holding pad. The cell collection devices have indicia markings on both sides that indicate the correct location of finger placement to pick up and utilize the device, and the location of cell collection. The indicia for locating finger placement are important to prevent inadvertent sample contamination to the first and second cell collection locations on the cell collection device. Examples of contaminants that can damage the cell collection location include finger oils and dirt, hand soap and hand lotion residues, fingernail polishes and other cosmetic product residues commonly found on the fingers or on the hand of a home user. The cell collection locations of the cell collection devices may also contain outer protective wrappings to protect the cell collection locations from external contamination until the user understands the instructions and is ready to proceed with cell collection.

[0018] The instruction sheet of the test component may be either a separate sheet within the component or may be an integral part of one of the surfaces of the sample container. For instance, the instructions may be printed on the outside surface of the foldable sample container. The instructions provide a sequence of detailed informative steps teaching the proper use of the test component to achieve accurate results. For example, detailed information about the proper method of picking up the first cell collection device, obtaining a sample from the inside surface

of a user's first cheek, placing the cell sample onto the indicia coordinated first holding pad of the sample container, and repeating the procedure for the same first cheek using the reverse side of the first collection device. Next, the previously described procedure is then followed for obtaining a sample for the inside surface of the user's second cheek using the second cell collection device and transferring the sample to the second holding pad of the sample container. Should a user be left-handed instead of right-handed, additional instruction about changes to the method of picking up and using a first and second cell collection device for use by a left-handed user are given. It is understood that obtaining a DNA sample is not limited to a buccal cell sample but can include DNA obtained from, but not limited to, other sources such as blood, urine, hair, skin, and other body fluids. If the cell collection locations on the cell collection devices contain outer protective wrappings, the instruction sheet would also contain additional instructions about the proper time of removal and method of removal of the outer protective wrapping before cell collection. The additional instructions about the outer protective wrapping would be inserted at the appropriate location within the sequence of instructions.

[0019] An outer pouch of the test component is sized to contain the sample container, which has coded indicia markings that indicate the identity of the user of the test component. The coded indicia markings may be used for several purposes such as, for example, maintaining user privacy, maintaining correct sample identity during preliminary sample preparation and analysis by the testing laboratory, and returning the specific genomic test results to the correct user.

[0020] A desiccant pillow of the test component may be included to maintain a relatively dry atmosphere within the outer pouch. The desiccant pillow includes a material for absorbing excess moisture from the atmosphere in the pouch. This prevents moisture from adversely affecting the cell samples that are disposed onto the sample holding pads located inside the folded sample container.

[0021] The drug metabolism test component incorporates indicia to alert a user that the test component is used to identify risk markers for predicting the probability of an adverse drug reaction. Particularly, it is the risk markers associated with the cytochrome P450 enzyme family. The cytochrome P450 enzymes are used in the metabolic processing of medication. Cytochrome P450 enzymes include the CYP3A gene family and CYP2D6. Identification of a user's risk markers is important because adverse drug reactions can result in liver dysfunction in some individuals. The risk markers are identified by examination of an individual's structural genes. In addition to the examination of the structural gene, genotypic testing of the regulatory/promoter regions, certain transcription factors and the gene sequences important for correct splicing will be performed. By this examination, the risk of dangerously large changes in liver function will be determined. By knowing what risk markers are present, the genomic analysis can be correlated to an effective drug therapy that minimizes the potential for an adverse drug reaction.

[0022] In order to maintain user privacy, a peelable label containing tracking indicia is removably affixed to the back side of the sample container. The sample

container also includes matching tracking indicia to that on the peelable label. Each test component has a unique tracking indicia.

[0023] The prescription instruction component directs the user/patient on how to obtain an initial dose of medical therapy for a particular affliction and a customized medical therapy based on the test results of the drug metabolism test component. The prescription instruction component can be provided with the drug metabolism test component as a companion product or located separate from the test component at a healthcare provider's office such as a doctor. The healthcare provider can dispense the test component with the prescription instruction component. The healthcare provider can dispense the prescription instruction component instructions separate from the test component. If the test component is not given to the user/patient by the healthcare provider, the prescription instruction component may contain instructions or directions that provide the user/patient with informative steps on how to obtain the drug metabolism test component over-the-counter or from a pharmacy by prescription. The prescription instruction component also explains how to obtain the initial dose of medical therapy, and a customized dose of medical therapy based on the results of the drug metabolism test component.

[0024] For example, the instructions may direct the user/patient to take the initial dose of medication if an initial dose is provided when receiving the drug metabolism test component or separately dispensed by a doctor. The prescription instruction component may direct the user/patient to obtain the initial dose by a prescription

issued by a healthcare provider concomitantly with the drug metabolism test component, or to have a healthcare provider communicate with other healthcare providers as necessary to obtain the initial dose from a pharmacy. The communication between or among healthcare providers can include a prescription by telephone, facsimile, computer or any other means used to communicate a prescription. This communication can be transferred by telephone, facsimile, computer or any other means used to communicate a prescription.

[0025] Also, the prescription instruction component directs the patient/user to only obtain, and healthcare providers to only dispense the customized dose of medical therapy based on the results of the drug metabolism test after the test results have been communicated to the appropriate healthcare provider. The healthcare provider may be, but is not limited to, a physician, dentist, nurse, pharmacist, physician's assistant, or nurse practitioner.

[0026] In one embodiment, the directed medication system and method incorporates an initial dose of medical therapy and a prescription for a customized medical therapy. In a second embodiment, the directed medication system and method incorporates only a combined prescription for an initial dose of medical therapy and for a customized medical therapy. In a third embodiment, the directed medication system and method incorporates separate prescriptions for an initial dose of medical therapy and for a customized medical therapy. In a fourth embodiment, the directed medication system and method incorporates only instructions for obtaining an initial dose of medical therapy and a customized medical therapy. In yet

another embodiment, the directed medication system and method incorporates an initial dose of medical therapy and instructions for obtaining a customized medical therapy.

[0027] The prescription for an initial dose of medication may be separate from or combined with a prescription for a customized medical therapy that is based on the results of the drug metabolism analysis. The prescription for a customized medical therapy may be separate from or combined with a prescription for an initial dose of medical therapy. The prescriptions for an initial dose of medication and for a customized medical therapy may be written or communicated by telephone, facsimile, computer or any other means used to communicate a prescription.

[0028] The prescription for customized medical therapy may be an individual prescription having multiple medical therapy dosage schedule parameters where each dosage schedule parameter is related to the results of the drug metabolism analysis. In the alternative, the prescription for customized medical therapy may involve separate prescriptions where each prescription has an individual medical therapy dosage schedule parameter related to the results of the drug metabolism analysis. The customized medical therapy dosage schedule parameters include a homozygous positive pattern that indicates dispensing of the prescribed dose, a heterozygous mid-positive pattern that indicates dispensing of an adjusted dose, and a negative pattern that indicates dispensing of a further adjusted dose or that a new medication should be dispensed. The customized medical therapy dosing schedule

parameters may include indicia that are letters, words, symbols, colors or any combination thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] FIGURE 1 is a perspective view of one embodiment of the directed medication system of the present invention.

[0030] FIGURE 2 is a top plan view of one embodiment of the test component of the present invention.

[0031] FIGURES 3 and 4 are top plan views of the embodiment in Fig. 2 showing different shaped sample holding pads.

[0032] FIGURE 5 is a back plan view of the embodiment in Fig. 2 showing the tracking indicia.

[0033] FIGURES 6A and 6B are enlarged front plan views of the embodiment in Fig. 2 showing the indicia on the buccal cell swabs.

[0034] FIGURES 7 is a top plan view of one embodiment of the prescription instruction component of the present invention.

[0035] FIGURE 8 is a top plan view of another embodiment of the prescription instruction component of the present invention showing a prescription for a customized medical therapy.

[0036] FIGURES 9A and 9B are top plan views of another embodiment of the prescription in Fig. 8 showing multiple dosage schedule parameters for a customized medical therapy.

[0037] FIGURES 10 is a top plan view of the initial dose prescription of the present invention for a customized medical therapy.

[0038] FIGURE 11 is a top plan view of the prescription instruction component of the present invention showing an initial dose and a conditioned prescription having multiple dosing schedule parameters for a customized medical therapy based on the results of the drug metabolism test component.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0039] The preferred embodiment(s) of the present invention are illustrated in Figs. 1-11. Figure 1 illustrates the broadest conceptualization of the directed medication system **1**. System **1** includes a drug metabolism test component **10** and a prescription instruction component **300**. Drug metabolism test component **10** is used to receive a patient/user biological sample that is analyzed providing a drug

metabolism test result. Preferably, drug metabolism test component **10** is a genomics-based test. Prescription instruction component **300** has a fulfillment characteristic that is directed by the results obtained from the genomics-based test component **300**.

[0040] Figure 2 illustrates front planar views of the preferred genomics-based test component **10**. The genomics test component **10** is specific for determining the presence of adverse drug reaction risk markers in a user's DNA. Genomics-based test component **10** includes a sample container **20**, a pair of buccal cell swabs **30**, instruction sheet **40**, an outer pouch **50**, and a desiccant **60**. Sample container **20** includes a first sample holding pad **22** and a second sample holding pad **24**. Sample container **20** is generally a hinged folder having a creased fold **26**. Creased fold **26** divides sample container **20** into an upper portion **26a** and a lower portion **26b** of approximately equal size. Upper portion **26a** has a securing tab **27** that may either fold over lower portion end **29** of lower portion **26b** or inserted into a lower portion slit **29a**. Securing tab **27** may also have a pressure-sensitive adhesive **28** to secure tab **27** against the back side (not shown) of lower portion **26b** near lower portion end **29**.

[0041] Sample holding pads **22** and **24** are generally impregnated with chemicals to lyse cell membranes and immobilize nucleic acids. Buccal cell swabs **30** are used for obtaining a buccal cell sample. Typically, buccal cell swabs **30** are made of wood to scrape a sample of epithelial cells from the inside cheek of a user. It is particularly important to include indicia **32** on each of cell swabs **30** to prevent sample contamination and to increase the probability of proper user compliance. Swabs **30**

include indicia **32** on each side of the swab. Indicia **32** link the test sample to be collected with the associated sample holding pad **22** or **24**.

[0042] Test component instruction sheet **40** includes instructions **42** that provide a sequence of detailed informative steps instructing in the proper use of the test component **10** to achieve accurate adverse drug reaction risk marker test results. The instructions include the use of linking indicia **32'** to guide the user in use of swabs **30** and proper sample collection and transfer techniques as well as disclosing the type of test component, i.e. to identify in a person's DNA the presence of risk markers that increase the probability of a particular drug causing liver dysfunction and leading to an adverse drug reaction. Test component instructions **42** provide detailed information about picking up the first swab or cell collection device **30**, obtaining a sample from the inside surface of a user's first cheek and placing the obtained sample onto the proper holding pad **22**, **24** as identified by the indicia **32** and **32'**.

[0043] Outer pouch **50** is a sealable container sized to receive sample container **20** for transfer to another location. Desiccant **60** is a standard moisture-absorbent pillow sized for placement within outer pouch **50** along with sample container **20**. Desiccant **60**, when placed within outer pouch **50** with sample container **20**, maintains a relatively dry atmosphere within outer pouch **50**. The desiccant material is typically a substance having a high affinity to water molecules that binds and holds the water molecules found in the atmosphere within outer pouch **50**.

[0044] Turning now to Figure 3, there is shown another embodiment of the sample container of the present invention. Sample container **80** includes a first sample holding pad **82** and a second sample holding pad **84**. Sample container **80** is generally a hinged folder having a creased fold **86**. Creased fold **86** divides sample container **80** into an upper portion **86a** and a lower portion **86b** of approximately equal size. Upper portion **86a** has a securing tab **87** that may either fold over lower portion end **89** of lower portion **86b** or inserted into a lower portion slit **89a**.

[0045] In this embodiment, test component instructions **42** are imprinted on a second surface **86a'** of upper portion **86a**. Indicating indicia **92** and **94** links the sampling instructions **42** for first and second cheek samples with the properly identified first and second holding pads **82**, **84**. Sample container **80** also has indicia **96** clearly identifying the adverse drug reaction risk marker kit.

[0046] Figure 4 shows yet another embodiment of the sample container of the present invention. Sample container **120** includes a first sample holding pad **122** and a second sample holding pad **124**. Sample container **120** is generally a hinged folder having a creased fold **126**. Creased fold **126** divides sample container **120** into an upper portion **126a** and a lower portion **126b** of approximately equal size. Upper portion **126a** has a securing tab **127** that may either fold over lower portion end **129** of lower portion **126b** or insert into a lower portion slit **129a**.

[0047] Like the embodiment in Fig. 3, test component instructions **42** are imprinted on a second surface **126a'** of upper portion **126a**. Indicating indicia **132**

and **134** may also connect the sampling instructions **42** for right and left cheek samples with the properly identified first and second holding pads **122**, **124**. Additional linking indicia **135** may be used to further link relevant portions of instructions **42** to sample holding pads **122** and **124**. Sample container **120** also has indicia **136** clearly identifying the adverse drug reaction risk marker kit. Sample container **120** further includes a first holding pad **122** that has a different shape than second holding pad **124**. In this example, the first holding pad **122**, labeled Left Cheek, has a square shape. Second holding pad **124**, labeled Right Cheek, has a circular shape. This shape differentiating indicia **135** is also included on swabs **30**, which further helps the user in reducing contamination by visually connecting the additional indicating indicia to the swabs **30** for use with the proper holding pad **122** or **124**.

[0048] Figure 5 is a back view of sample container **20**. On a back surface **21**, there is imprinted indicia **96** to indicate the type of test, indicia **72** for tracking the sample, a mailing address of the place for analysis, and a removable, peel-off sticker **70**. Removable sticker **70** includes tracking indicia **72** for the user to obtain the results of the test while maintaining user privacy.

[0049] Figures 6A and 6B illustrate the indicating indicia on swabs **30**. Turning now to Fig. 6A, right cheek swab **30'** has a first swab side **34** and a second swab side **36**. Swab sides **34**, **36** have imprinted thereon adjacent a swab end **33**, indicia **32** indicating the sample holding pad associated with right cheek swab **30'**. In this particular example both the shape and the word symbols indicate the proper sample

holding pad for receiving the right cheek sample. In Fig. 6B, left cheek swab **30"** also has a first swab side **34'** and a second swab side **36'**. Adjacent a swab end **33'**, indicia **32** are imprinted to indicate the sample holding pad associated with left cheek swab **30"**.

[0050] Turning now to Figures 7-11, there is illustrated various embodiments of the prescription instruction component **300** of the directed medication system **1** that includes an instruction component **302**, a prescription component **340**, or both. Instruction component **302** may be verbal instructions provided by the healthcare provider to the patient, but is preferably written instructions provided to the patient. Figure 7 illustrates one embodiment of a basic prescription instruction component **300** comprising only of an instruction component **302** that is received by a patient from a healthcare provider. In this embodiment, prescription instruction component **300** includes a first instruction **304** that directs the patient to obtain a drug metabolism test component **10** and to follow the test component instructions to submit a test sample for testing. A second instruction **306** directs the user/patient to obtain a customized medical therapy after the results of test component **10** are presented to the user/patient's healthcare provider.

[0051] The manner in which the results of test component **10** are presented to the healthcare provider may vary. For example, the test results may be sent directly to the patient. In this case, the patient would present the test results to an appropriate healthcare provider to obtain the proper medical therapy. The test results may also be communicated directly to the patient's healthcare provider. This would likely

improve efficiency of the directed medication process. Another alternative would be to have the test results sent directly to the pharmacy. Depending on the particular embodiment of the directed medication system, the pharmacist would either fill an existing, conditional prescription based on the results of the test or call the patient's healthcare provider and communicate the test results to the healthcare provider at which time the healthcare provider would issue a customized medical therapy to the pharmacist based on the test results. The pharmacist would then dispense the customized medical therapy to the patient.

[0052] Instruction component **302** may be modified in accordance with the embodiment used to carry out the method of the present invention. For instance, the drug metabolism test component **10** may be an over-the-counter item or may be obtained by prescription or directly from a healthcare provider. Further, the prescription component **340** may be included in various embodiments. All of these variations will impact the structure/arrangement of the prescription instruction component **300**.

[0053] Figure 8 illustrates an embodiment of the prescription instruction component **300** that includes a prescription component **340**. In this embodiment, prescription component **340** is a prescription **342** issued by a healthcare provider. Prescription **342** includes a conditional prescription portion **344** instructing the pharmacist to dispense the medical therapy pending the results of the drug metabolism test component **10**.

[0054] A more efficient way to carry out the intent of the present invention is illustrated in Figures 9A and 9B. Fig. 9A shows a prescription component **340** that includes a prescription portion **344**. Prescription portion **344** includes multiple, dosing parameter instructions **346** to the pharmacist based on the results of the drug metabolism test component **10**. The multiple dosing parameter instructions **346** includes a homozygous positive instruction **346a** that indicates dispensing of the prescribed dose, a heterozygous mid-positive instruction **346b** that indicates dispensing of an adjusted dose, and a negative instruction **346c** that indicates dispensing of a further adjusted dose or that a new medication should be dispensed.

[0055] Turning now to Fig. 9B, there is shown variation of the prescription component **340** shown in Fig. 9A. Prescription component **340** includes a first conditional prescription **346a'**, a second conditional prescription **346b'**, and a third conditional prescription **346c'**. First conditional prescription **346a'** is equivalent to homozygous positive instruction **346a** and indicates dispensing of the prescribed dose only if a positive result is obtained from the drug metabolism test. Second conditional prescription **346b'** is equivalent to heterozygous mid-positive instruction **346b** and indicates dispensing of an adjusted dose only if a mid-positive result is obtained. Third conditional prescription **346c'** is equivalent to negative instruction **346c** and indicates dispensing of a further adjusted dose or that a new medication should be dispensed only if a negative result is obtained.

[0056] In certain healthcare situations, it is preferable that the patient at least receive an initial dose of medication to begin treatment pending the results of the

drug metabolism test component **10**. Typically, an initial dose in these situations will not produce an adverse drug event until additional doses are taken. It is the additional doses that increase the level of medication in a patient whose system is unable to properly metabolize the medication at the level taken that leads to the adverse drug event.

[0057] Figure 10 illustrates another embodiment of the prescription component **340**. Prescription component **340** includes an initial dose prescription **350** along with the conditional prescription. Initial dose prescription **350** authorizes the pharmacist to dispense an initial dose of the medical therapy medication but not to dispense or fill any additional dosages until the results of the drug metabolism test component **10** are received. It is noted that, in addition to being a written prescription, initial dose prescription **350** may also be a prescription that has been communicated by telephone, facsimile, computer such as for example by email, or any other means used to communicate the prescription. An alternative to providing initial dose prescription **350**, the healthcare provider may dispense the initial dose **350'** of medication directly to the patient along with prescription component **340** that includes a prescription portion **344** of prescription component **340** that includes a first conditional prescription **346a'**, a second conditional prescription **346b'**, and a third conditional prescription **346c'**, as illustrated in Fig. 11.

[0058] As contemplated by the present invention, the directed medication system **1** may be in a kit form provided by healthcare provider or by prescription. In the alternative, the directed medication system **1** may be a combination of an over-the-

counter test component **10** linked or coupled to prescription instruction component **300**.

[0059] To use the preferred embodiment of the directed medication system **1**, the user/patient obtains a drug metabolism test component **10** that is preferably a genomics test kit either directly from a healthcare provider such as a medical doctor or by prescription from a healthcare provider such as a pharmacist or from the pharmacy as an over-the-counter item. The patient also obtains an initial dose **350'** of medical therapy and a conditional prescription **340** from the patient's doctor, which is to be filled based on the results of the test component **10**.

[0060] The user opens test component **10** and removes swabs **30** that have indicating indicia **32** on each side. In this case, indicating indicia **32** are "Right Cheek #1," "Right Cheek #2," "Left Cheek #1," and "Left Cheek #2." The user takes swab **30** marked "Right Cheek #1," places the user's thumb over the words that say "Right Cheek #1," and puts the swab into the user's mouth placing the flat surface against the inside of the right cheek. The user then gently rubs the tip of the swab up and down five times with a motion of about one-half of an inch. This motion results in a few cells lining the inside of the right cheek to stick to swab **30**.

[0061] The user removes swab **30** from the mouth and swirls the tip of swab **30** containing the cells about ten times onto the second holding pad **24** marked "Right Cheek." Using the same swab **30**, the user is instructed to repeat the process by now placing the user's thumb over the words that say "Right Cheek #2." After rubbing the tip of swab **30** against the inside of the right cheek, the user swirls the tip

of swab **30** containing more cells about ten times onto the first holding pad **24**. This process is repeated for the left cheek using swab **30** marked "Left Cheek #1" and "Left Cheek #2."

[0062] Upon completion of sample collection, the sample container **20** is sealed by folding upper portion **26a** over lower portion **26b** and securing upper portion **26a** to lower portion **26b** using securing tab **27**. The user then removes the peel off tracking number and retains it for reference purposes, and mails the sample container **20** to the indicated address for analysis. It is understood that if the results are to be communicated directly to the patient's pharmacy or healthcare provider, then the appropriate forwarding information will need to be included when submitting the test sample for analysis.

[0063] In the preferred embodiment, the results of the test, which is also known as the genomics analysis or the genomics information, are then communicated to either the patient or the patient's healthcare provider who then communicate the test results with other healthcare providers as necessary to customize the medical therapy based on the test results. The customized medical therapy is only dispensed after the test results have been communicated so that the healthcare provider can dispense the appropriate medical therapy based on the test results. The medical therapy is customized according to the test results of the genomics analysis. If the genomics analysis indicates a homozygous positive pattern the prescribed dose is dispensed. If the genomics analysis indicates a heterozygous mid-positive pattern an adjusted dose is dispensed. If the genomics analysis

indicates a negative pattern a further adjusted dose is dispensed or a new medication is dispensed.

[0064] Although the preferred embodiments of the present invention have been described herein, the above description is merely illustrative. Further modification of the invention herein disclosed will occur to those skilled in the respective arts and all such modifications are deemed to be within the scope of the invention as defined by the appended claims.